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ARMSTRONG LABORATORY

TEST AND EVALUATION OF THE IMPACT INSTRUMENTATIONS,INC. UNI-VENT MODEL 750M VENTILATOR

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Systems Resource Branch
2504 Gillingham Dr, Ste 1
Brooks AFB TX 78235-5104

November 1994

Interim Technical Report for Period October 1993 - June 1994

Approved for public release; distribution is unlimited.

AIR FORCE MATERIEL COMMAND
BROOKS AIR FORCE BASE, TEXAS

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This report has been reviewed and is approved for publication.

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13. ABSTRACT *(Maximum 200 words)*
The Aeromedical Research Function tested and evaluated the Uni-Vent 750M ventilator for use on aeromedical evacuation aircraft in response to a request from the Director, Aeromedical Evacuation and Medical Plans and Requirements, Human Systems Center at Brooks AFB. A collaborative evaluation was conducted with the U.S. Army Aeromedical Research Laboratory, Ft Rucker, Alabama. The Impact Instrumentations, Inc. Uni-Vent Model 750M ventilator was found acceptable for use on cargo aircraft used for USAF aeromedical evacuation.

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I would like to thank all those who helped and advised during the evaluation of the Impact Instrumentation, Inc., Uni-Vent Model 750M ventilator. I would especially like to thank Lt Col Jacqueline Hale, 1Lt Philip Preen, TSgt Butch Blake, TSgt Allen Jones, and crews from the 31 AES Charleston AFB, 32 AEG Kelly AFB and 57 AES Scott AFB. Dr. Johaningman, and the Respiratory Therapy Department at Wilford Hall Medical Center (SSgt Ward, TSgt Pleasants).

TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC. UNI-VENT PORTABLE VENTILATOR MODEL 750M

BACKGROUND

Air Training Command Surgeon General and the Department of Surgery, Wilford Hall USAF Medical Center, briefed HQ AMC/SG (Brig Gen Roadman) on the feasibility of a Critical Care Aeromedical Transport Team (CCATT). During this meeting a request for evaluation of a ventilator for air worthiness was presented. The Director, Aeromedical Evacuation and Medical Plans and Requirements, requested the Human Systems Center at Brooks AFB evaluate the Impact Instrumentations, Inc. Uni-Vent model 750M ventilator. This piece of equipment is being evaluated as part of a cooperative effort between U.S. Air Force Armstrong Laboratory, Aeromedical Research and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama. Electromagnetic interference, vibration and environmental testing were conducted at the Fort Rucker facilities. We conducted battery performance, human factors, altitude and rapid decompression testing at our facilities. The inflight feasibility evaluation was conducted on Air Force aeromedical aircraft.

DESCRIPTION

The Uni-vent portable ventilator, Model 750M, hereby referred to as Impact 750M, is a portable, electronically controlled, time-cycled, pressure-limited ventilator (Fig. 1). It is controlled by an on-board microprocessor that continuously monitors the patient's airway pressure, all control settings, alarm parameters and power signals. The Impact 750M is operable from internal, rechargeable batteries: 11-30 volts AC or DC, positive or negative ground, 50 to 400 Hz. Its battery pack may be recharged within the range of either of the aforementioned AC or DC voltages. A 115/230 VAC, 50-400 Hz Multivoltage AC power supply and 12 VDC power cable are provided. The Impact 750M can deliver gas from a compressed gas cylinder, oxygen blender, electric compressor, PTLOX (Portable Therapeutic Liquid Oxygen) or on-board aircraft generated oxygen source. Acceptable input gas pressures to the control module may range up to 100 psi, however, FLOW ADJUST control labeling is based on a 50 psi input. (See WARNINGS REGARDING USE in instruction manual.) The Impact 750M does not consume gas for operating power. It can provide ventilatory support in CONTROL, ASSIST-CONTROL and SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV) modes. Each mode is operable with or without sigh or PEEP (Positive End Expiratory Pressure). Multiple alarm systems are included. See Appendix A for size and weight specifications. The Model 750M includes a carrying case with the following components: Control module (SN 9306012), patient valve, high pressure hose, spiral hose - 10mm I.D., hose - 1/8" I.D., hose - 3/16" I.D., multivoltage AC Power supply, 12 VDC power cable with military connector and battery pack.

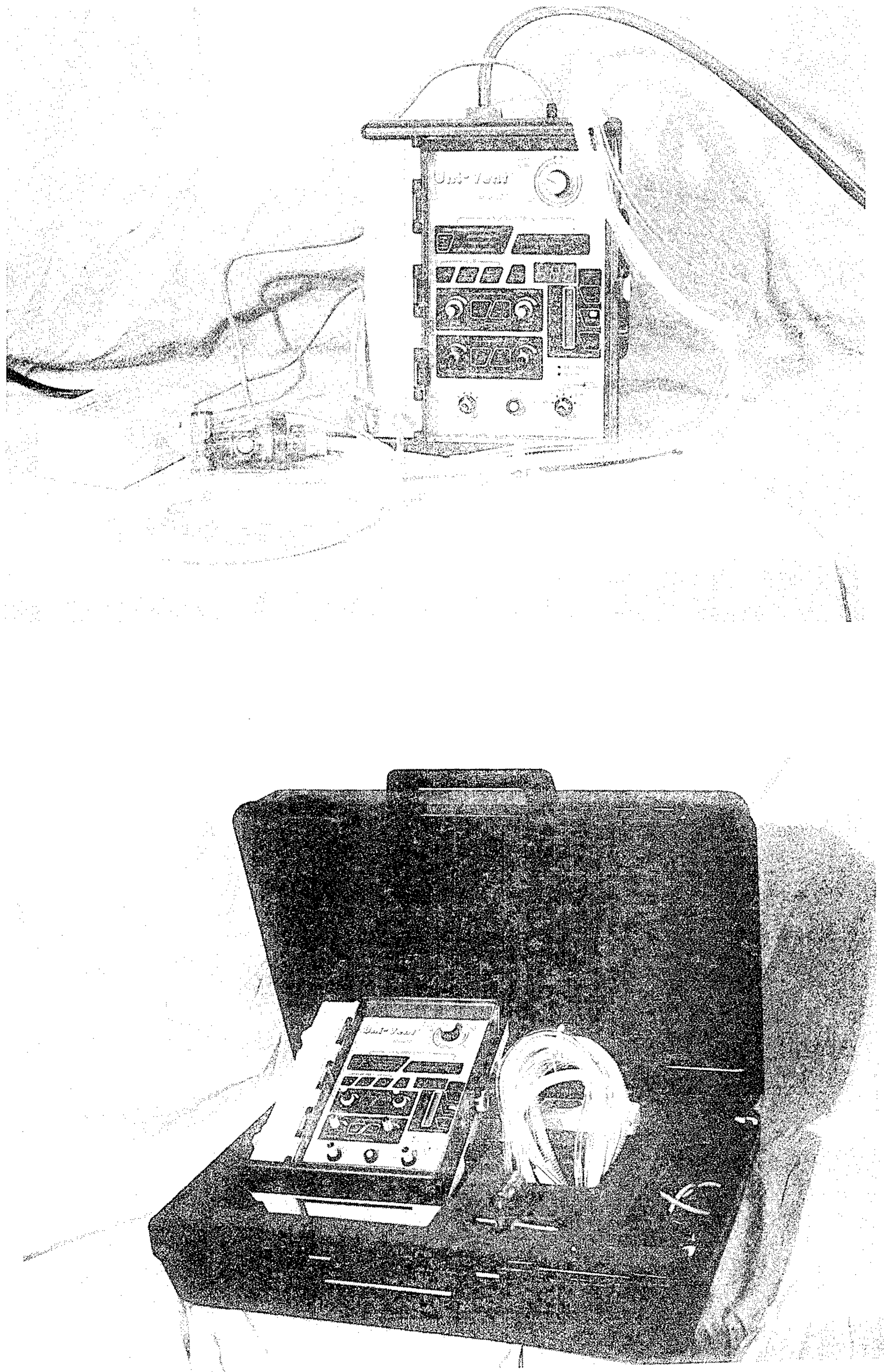

Figure 1. Uni-Vent portable ventilator, Model 750M

METHODS

Test methods and performance criteria were derived from various military standards (Reference List, 1-2), nationally recognized performance guidelines (3), and Uni-Vent 750M portable ventilator operation and service manual (4). Procedures covering safety and human factor issues have been developed by Aeromedical Research personnel (5). A test setup and a performance check were developed to verify proper functioning of the equipment under various conditions.

Test Setup

Using the patient breathing circuit provided by the manufacturer (used throughout our evaluation), the ventilator was connected to a Bio-Tek Instruments Model VT-2 Ventilator Tester. An Airdyne air compressor was connected to the gas inlet port on the Impact 750M. The power cord was plugged into an AC wall outlet and corresponding "EXT POWER' receptacle on the unit. The ventilator controls were set as follows: Flow Adjust Knob @ 800 ml/sec; BPM rate @ 16; Inspiration Time @ 1.0; Assist/SIMV sensitivity @ -.2; Mode @ Control; High Pressure Alarm @ 70; and Low Pressure Alarm @ 10. The VT-2 settings were as follows: Resistance @ 20; Compliance @ .05 L/cm H20; pressure units in centimeters of water; Relative Humidity @ 50%; Atmospheric Pressure @ ground level testing set for 747 mmHg (during altitude testing the VT-2 was reset to correspond to the atmospheric pressure at each test position); and Gas temperature @ 25°C.

Performance Checks

The following performance check was used to validate the function of the Impact 750M in each of the test conditions, unless otherwise stated. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. Using the Bio-Tek VT-2 ventilator analyzer, a Full Test was used to measure and record 15 parameters. The Full Test mode included the following: breath rate, inspiratory to expiratory ratio (I:E ratio), tidal volume, minute volume, inspiratory time, inspiratory hold time, expiratory time, expiratory hold time, cycle time, peak airway pressure, peak lung pressure, end expiratory pressure, mean airway pressure, inspiratory flow rate, and expiratory flow rate.

Three Full Tests were run and recorded at 5-minute intervals, before and after each laboratory test. During each laboratory test, at 15-minute intervals, a Full Test was run and the parameters were recorded. Values derived from the 3 pretest recordings were used as a baseline reference in determining variation percentages recorded during testing. Post-performance check values were used to identify any deviation from the pre-performance check that might indicate damage to the ventilator due to testing.

Battery Performance Test

The 12 VDC internal battery is rated for approximately 9 hours of operation and recharge time ranges from 14-16 hours, depending upon initial stage of discharge. Continuous charging is permissible with the 12 VDC power cable, 115 VAC/60Hz and 115 VAC/400 Hz AC power supply.

From a full charge, the Impact 750M was run on battery power until the low battery alarm activated. A performance check was done once every 45 minutes during this period. The unit was turned off and the batteries were charged on 115 VAC/60 Hz. After recharging for 14-16 hours, the unit was run on battery power until the low battery alarm activated. Battery voltage was monitored with a Grant (Squirrel) data logger. The same procedure was repeated using 115 VAC/400 Hz to recharge the batteries.

Altitude

The Impact 750M was tested to see the effects of reduced barometric pressure in the Armstrong Laboratory altitude chambers (Bldg. 160, Brooks AFB, TX.) The testing consisted of operating the equipment while connected to the VT-2, stopping at intervals, every 2,000 feet, up to 10,000 feet to ensure its continued operation and compliance with the prescribed operating parameters. The VT-2 transducers were zeroed at each stop and the atmospheric pressure reading was changed to record the current pressure. The ventilator was given time to stabilize at each altitude and 3 Full Tests were accomplished at 5-minute intervals.

Rapid Decompression (RD)

The purpose of this test was to approximate the stress that medical equipment is exposed to during normal, emergency, and accidental decompression. Protocol involves ascending to 8,000 feet at a minimum of 5,000 feet per minute, then decompressing to 40,000 feet in 60 seconds while observing equipment performance. The chamber was returned to ground level and three Full Tests were accomplished. This test was repeated for 7- and 1-second rates of decompression. The ventilator was placed inside the test chamber connected to a Manley Lung simulator using the same settings for performance check. Visual observation of the pressure gauge was done through a window to monitor maximum pressure delivered at the time of decompression. The VT-2 was outside the test chamber and used to obtain test data at the end of each RD.

Airborne Feasibility

Inflight feasibility tests were conducted to develop and/or verify medical equipment operating procedures and to validate operational performance of the equipment in the actual aeromedical evacuation environment. Inflight testing was conducted on USAF C-9A, C-130, and C-141 aircraft. Oxygen from the on-board therapeutic system of the C-9A/C-141 was attached to the ventilator, providing 50 ± 5 psi. On the C-9A, the system was powered by the 115 VAC/60 Hz aircraft power. On

the C-141, the system was powered by the 115 VAC/400 Hz aircraft power. On the C-130, the system was powered using its battery operation since the electrical requirements are the same as the C-141. A PTLOX was unavailable for flight, so an alternative pressurized gaseous oxygen source, with 50 psi, was used on the C-130. Ground evaluation with a PTLOX was later accomplished to determine compatibility with the ventilator.

Setup and securing methods, integration with aircraft oxygen and electrical systems, and use and storage of the carrying case were evaluated. Crew acceptability was assessed during evaluator's interaction with the medical crews.

RESULTS

The Impact Uni-Vent 750M was tested first by the United States Army Aeromedical Research Laboratory (USAARL), located at Fort Rucker Alabama. Test results from USAARL were reviewed and found acceptable to meet USAF standards for vibration, electrical safety, and environmental parameters. The Impact 750M does not meet the Air Force requirements outlined in MIL-STD-461D for electromagnetic interference (EMI). The unit has been granted a waiver for use on USAF large bodied cargo aircraft (C-9A, C-141, C-130). EMI testing has shown the unit may interfere with VHF/FM and HF frequencies due to excessive radiated emissions. The waiver is approved by ASC/ENAI, Wright-Patterson AFB, Ohio, with recommendations for use on aircraft. (Atch 1)

Battery Performance

The unit passed testing, lasting according to manufacturer guidelines (Appendix A).

Altitude

Altitude testing identified the preset tidal volume (V_t) to increase by 29% while ascending to 10,000 feet. Upon returning to ground level the tidal volume returned to its preset value. The graph below shows the rise in tidal volume while ascending and descending in altitude (Fig. 2).

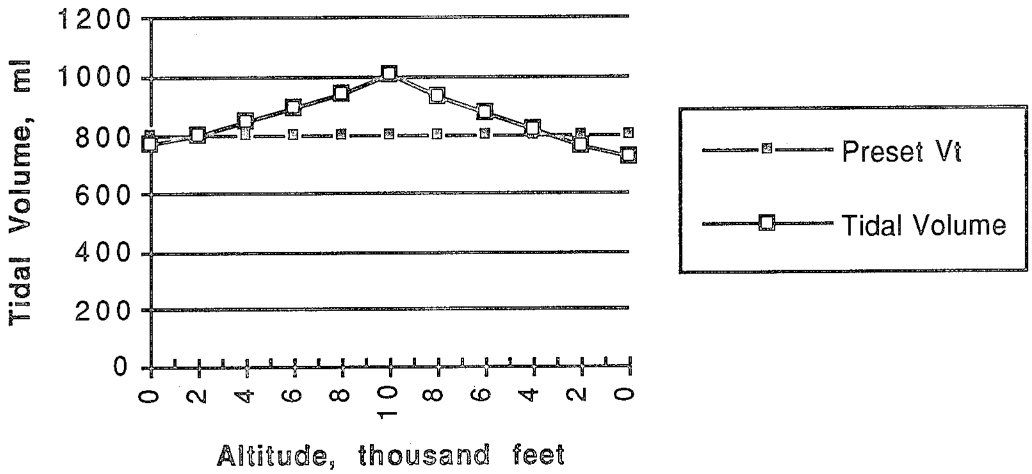

Fig. 2 Actual tidal volumes at simulated altitudes

Rapid Decompression

During the 1-second decompression, the ventilator FAL alarm occurred and the unit ceased functioning. The chamber was returned to ground level, the unit was reset according to manufacturer's instructions and operation was resumed. No problems were encountered while performing the 60- and 7-second rapid decompressions. The unit's high-pressure alarm was set at 100 and the pressure relief valve performed according to manufacturer's specifications.

Airborne Feasibility

This evaluation confirmed that the Impact 750M ventilator will successfully function on the C-9A, C-130 and C-141 aircraft, provided special adapters are with equipment for set-up. Below is a detailed summary for each aircraft. The ventilator was easy to enplane and deplane on each of the aircraft. It is compatible with the electrical systems used on each aircraft.

C-9A: An oxygen hose with a Schrader adapter at one end and female adapter at the other end is needed for obtaining oxygen from a C-9A wall mount. The mounting bracket on back of the unit is not compatible with the wall bracket on the aircraft. The angle of the fuselage prevents the unit from attaching. The manufacturer provided two separate brackets for evaluation (see Fig. 3). We evaluated both, finding each to be beneficial for securing. Figures 4 and 5 show the spacer mounting bracket on the C-9A fuselage and with the ventilator secured, respectively. We also utilized the Waters bracket (AL-TR-1992-0086) and were able to secure the ventilator without interfering with its controls. Visual alarms could be seen by crew and audible alarms

were heard at approximately 30 ft. When moving patient with ventilator, it will be necessary to have a transportable oxygen source.

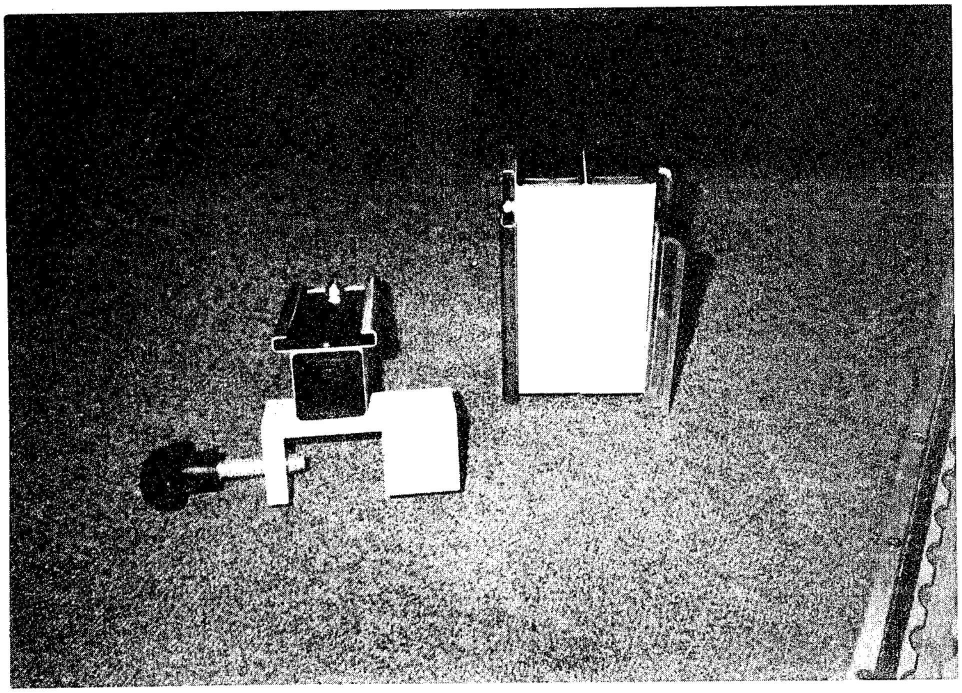

Fig. 3 Securing Brackets for Impact 750M

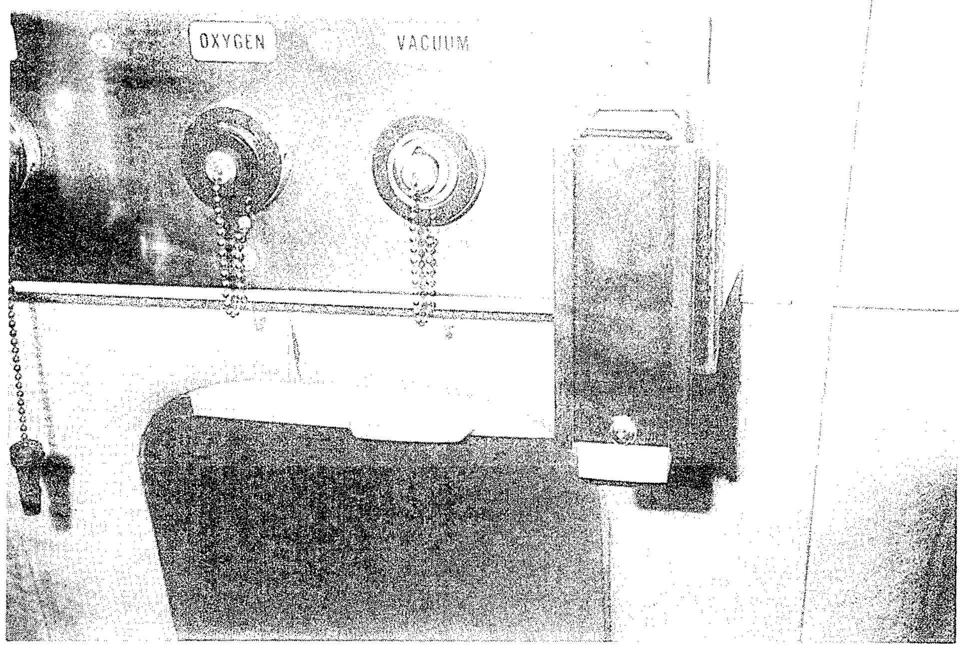

Fig. 4 Spacer mounting bracket on C-9A fuselage

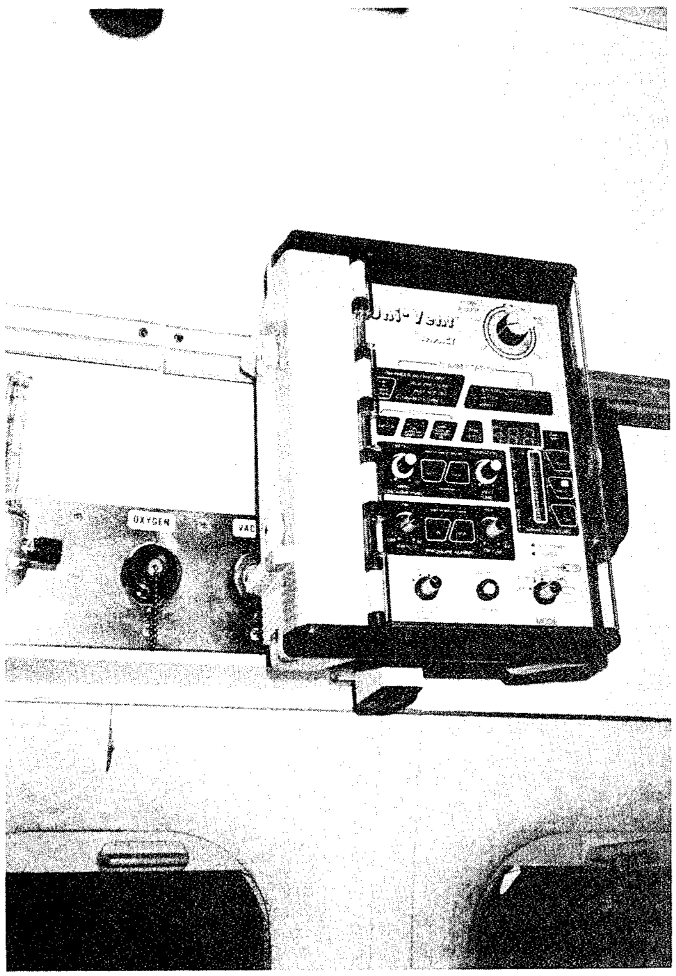

Fig. 5 Impact 750M secured on C-9A fuselage

C-130/C141: The PTLOX can provide the necessary oxygen source on board the C-130. The PTLOX oxygen hose will interface with the Impact 750M. On the C-141, the ventilator will require an oxygen hose that has a female adapter at each end to be compatible with this oxygen system. We tested several different methods of securing the unit on the C-130/C-141. If the Waters bracket is used, the unit can be positioned facing a crew member for continuous observation of the visual alarms. The Horton bracket can also be used with the pole mount bracket available from the manufacturer. Figure 6 shows the ventilator secured to a Horton bracket on the C-130. The ventilator should be positioned for crew detection of visual alarms since the audible alarms could only be heard for approximately 8 ft.

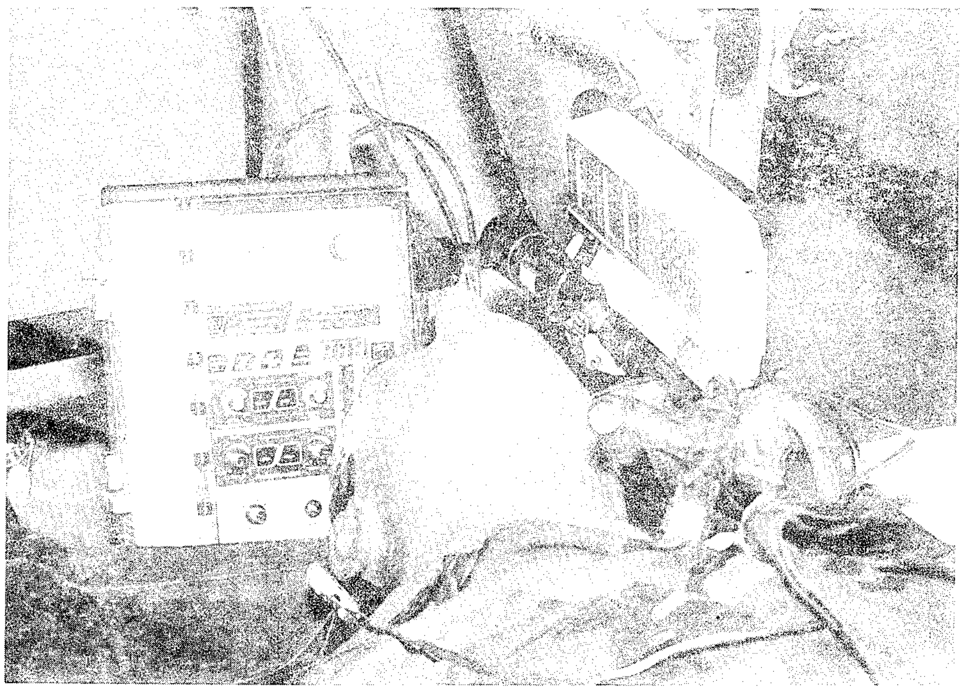

Fig. 6 Ventilator secured with Horton bracket on C-130

General observations:

1. Unit placement is restricted by constraints of ventilator tubing.
2. When securing with litter straps, the unit cannot be placed for easy observation by crew, and access to control knobs is blocked by the straps.
3. The spiral hose, 10 mm I.D., is smaller than the current patient tubing used in the aeromedical evacuation system. (Disposable tubing is available from company.) The patient valve is not disposable and must be sterilized after use.
4. Adapters are needed for placement of any special equipment to be added inline with the ventilator tubing, eg., Mini-Ox III, temperature gauge, heat moisture exchanger.
5. Special equipment is needed for oxygen interface.
6. Securing brackets obtained from the manufacturer would be beneficial for securing the ventilator.

CONSIDERATIONS

In consultation with personnel from the Respiratory Therapy Department, Wilford Hall Medical Center, several items of interest were addressed concerning additional equipment required to transport a patient on an extended flight. As shown in Fig. 7, the set-up of tubing would include a heat moisture exchanger (HME). Also seen is a hand-held respirometer. Since the ventilator increases the tidal volume delivered to the patient while at altitude, the respiratory technician would require a respirometer to verify patient volume delivery and make adjustments to the unit as appropriate. The respirometer is usually carried by the technician who is accompanying the patient. If the patient requires blended air, a pulse oximeter could be used to estimate the patient's FI02, instead of using the Mini-OX III in line. This would avoid the requirement for adapters.

The respiratory therapy personnel noted some problems with cleaning the patient valve by heat sterilization. Hazing of the patient valve occurred, causing stress fractures and weakness around attachment ports. They also noted that the mushroom valve located inside the patient valve can be screwed up and down, and if improper placement should occur, it may cause an artificial PEEP, or block off air delivery to the patient. This valve should be checked for proper placement prior to each patient use.

While transporting ventilator patients via Gurney within the hospital, with a PEEP setting, a PEEP not set alarm would occur while traveling in the elevator. To override this the PEEP Manual display/set was used.

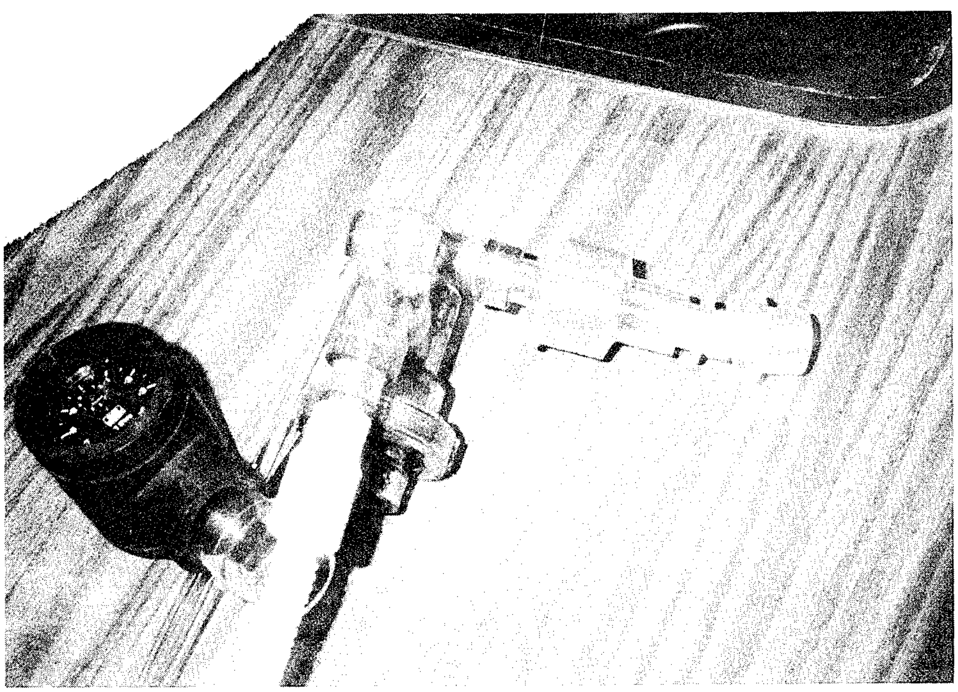

Fig. 7 Patient valve with HME

RECOMMENDATIONS

1. A heat moisture exchanger should be used for breathing gas humidification.
2. Respiratory technician should be required to monitor tidal volume while inflight to adjust unit appropriately.
3. For ease of securing ventilator on aircraft, purchase securing devices provided by manufacturer: Pole mount part # 704-0750-08 and standard wall mount part # 704-0750-07 with 1 1/4" square spacer (modified for use on C-9A).
4. The following notes and warnings should be added in the Operation and Service manual.
   a. NOTE: Check the diaphragm valve located in the patient valve for proper placement prior to connecting patient to ventilator. Turn on the unit and cover the patient port to cause some resistance and look at the airway pressure digital bar graph for positive pressure being delivered to the patient.
   b. NOTE: Heat sterilization may cause hazing of the patient valve. Carefully inspect prior to patient use to ensure all attachment ports will withstand use.
   c. WARNING: If a rapid decompression occurs, the FAL alarm could occur. Manual respiration must be assumed and the ventilator reset according to manufacturer's instructions.
   d. WARNING: Restrictions for use on USAF large bodied cargo aircraft: For take-off and landing, operate the unit on battery power. During other phases of flight the ventilator may be operated on 60 Hz or 400 Hz power. Notify the pilot and crew that this equipment is in use.
   e. WARNING LABEL attached on unit: For take-off and landings use on battery power only.
5. Some type of locking pin device should be added to securing brackets for use after unit is placed within tracking.
6. For use only on C-9A, C-141, C-130 aircraft.

REFERENCES

1. MIL-STD 461-D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e.

2. MIL-STD 810-D, Environmental Test Methods and Engineering Guidelines.

3. ECRI, INDEX 1993

4. Impact Instrumentation Manual, Operation and Service, Rev. C (03/93)

5. Aeromedical Research Procedures Guide, Internal operating instruction, Armstrong Laboratory, Systems Research Branch.

6. Testing data results from U.S. Army Aeromedical Research Laboratory, Ft Rucker, Alabama.

APPENDIX A

SPECIFICATIONS AND OPERATING FEATURES

OF THE IMPACT UNI-VENT
MODEL 750M

SPECIFICATIONS AND OPERATING FEATURES OF THE IMPACT UNI-VENT MODEL 750M

Model: Uni-Vent 750M
Manufacturer: Impact Instrumentation, Inc.
27 Fairfield Place
West Caldwell, NJ 07006

Operating Modes: CONTROL-with/without PEEP, with/without SIGH
ASSIST-CONTROL-with/without PEEP, with/without SIGH
SIMV-with/without PEEP, with/without SIGH

Flow Rate: Adjustable, 0 to approximately 100 LPM @ 50 PSI (0 to approximately 1600 ml/SEC) (+/-10%)

Ventilation Rate: Adjustable, 1 to 150 breaths per minute, resolution 1 breath per minute increments (+/- digit on the display panel)

Inspiration Time: Adjustable, 0.1 to 3.0 seconds, resolution in 0.1 second increments (+/- 1 digit on the display panel)

Low Pressure Alarm: Adjustable, OFF to 50 cmH_20 (OFF), resolution in 1 cmH_20 increments (+/- digit on the display panel)

High Pressure Alarm: Adjustable, 10 to 100 cmH_20 (OFF), resolution in 1 cmH_20 increments (+/- digit on the display panel)

Peak Inspiratory Pressure Relief: Adjustable, 10 to 100 cmH_20 increments (+/- digit on the display panel)

Assist/SIMV Sensitivity: Adjustable, -2 to -8 cmH_20, resolution in -2 cmH_20 increments

Automatic Peep: Monitor range 1 to 20 cmH_20, resolution in 1 cmH_20 increments (+/- 1 digit on the display panel)

Manual Peep: Program range 1 to 20 cmH_20, resolution in 1 cmH_20 increments (+/- digit on the display panel)

Sigh: Initiates upon activation then once every 100-ventilations or 7-minutes thereafter, whichever occurs first. SIGH = 150% of inspiration time (truncated to a combined maximum of 3-seconds)

Alpha/Numeric Displays: RATE, INSPIRATORY TIME, LOW PRESSURE ALARM, HIGH PRESSURE ALARM, PEEP, AUTOmatic, PEEP MANual, PEAK AIRWAY PRESSURE, MEAN AIRWAY PRESSURE, Paw

Indicator Lamps: RATE, INSPIRATORY TIME, INSPIRATION, LOW PRESSURE ALARM, HIGH PRESSURE ALARM, PEEP OFF/ON, PEEP AUTOmatic, PEEP MANual,

SIGH OFF/ON, PEAK AIRWAY PRESSURE, MEAN AIRWAY PRESSURE, Paw, EXTERNAL POWER, POWER, ASSIST/SIMV ON

Digital Bar Graph: Display range -10 to 100 cmH_20, mixed resolutions

Alpha/Numeric Alarm Displays: INVERSE I/E, MEMORY CHECK, TRANSDUCER CALIBRATION, TRANSDUCER CALIBRATION ABORT, FAL

Alarm Indicator Lamps: LOW PRESSURE/DISCONNECT, HIGH PRESSURE, EXTERNAL POWER LOW/FAIL, BATTERY LOW/FAIL, PEEP NOT SET, APNEA, ALARM MUTE/CANCEL

Demand Flow: 60 LPM (+/-10%)

Manual Trigger: Operator controlled manual override of current operating mode

Operating Voltages: CONTROL MODULE: Input: 11-30 VDC (Positive or Negative ground); 11-30 VAC, 50-400 Hz.

Multivoltage AC Power Supply: Input: Selectable 115/230 VAC, 50-400 Hz. Output: Nominal 12 VDC, (Positive ground), 1.5 A (max)

Operating Time: Internal Batteries: 9-hours with standard battery pack 11-hours with optional battery pack
External AC: Continuous
External DC: Continuous

Temperature Ranges: Operating: -60°C to 60°C (-76°F to 140°F)
Charging: -20°C to 50°C (-4°F to 122°F)
Long Term Storage: 10°C to 30°C (50°F to 80°F)

Size: 9.0" Wide (9.4" including battery compartment locking ribs) X 11.5" High X 4.5" Deep
22.9 cm Wide (23.9 cm including battery compartment locking ribs) X 29.2 cm High X 11.4 cm Deep

Weight: Control Module: Less than 10 lbs (including battery) (less than 4.5 kg)
Multivoltage AC Power Supply: 2.5 lbs (1.14 kg)

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AERONAUTICAL SYSTEMS CENTER (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

25 Jun 94

MEMORANDUM FOR AL/CFTS
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BROOKS AFB TX 78235-5104

FROM: ASC/ENAI
Building 20
2450 D Street Suite 2
Wright-Patterson AFB OH 45433-7630

SUBJECT: Electromagnetic Interference (EMI) Certification for the Impact Uni-Vent Portable Ventilator, model 750

1. We have reviewed the subject data and recommend using the ventilator on large body aircraft only, and during take off and landing (below 10,000 ft.) the ventilator should be operated on batteries. We recommend this because the ventilator meets AF radiated emission requirements (RE02) when operated on internal battery. The ventilator can operate on 60 Hz, or 400 Hz during other phases of flight. The ventilator has emission in excess of MIL-STD-461 limits when powered externally. These emissions will not cause any degradation to flight safety and mission capability should not be affected for the large body aircraft. The pilot and crew should be aware that the equipment is being operated.

2. The RE02 test data reflects the limits imposed in MIL-STD-461A Notice 4 (Army notice). The Army's RE02 requirements are 10 dB more stringent than the Air Force's requirements levied for test method RE02 in MIL-STD-461A, B, C, or D.

3. The RF noise generated by the ventilator is not a concern for any onboard equipment other than antenna connected receivers (highly sensitive and intentional apertures -- antennae). The RF noise generated by the ventilator is in the frequency range of 19 MHz to 45 MHz, which covers the upper third of the HF radio band and the lower fourth of the VHF-FM radio band. Seventeen HF or VHF/FM channels, of roughly thirty seven hundred, could be degraded. There are no navigational receivers in this frequency range.

4. In response to your request for a detailed explanation why we allow relaxation of the radiated emissions for large body aircraft the answer is simply greater separation between the offending equipment and the victim's receiving antenna. Greater separation provides greater free-space "loss" (power density decreases): power received is inversely proportional to the

distance squared.

$$P_R = P_T \left[\frac{\lambda^2}{(16\ \pi^2)(D^2)} \right]$$

where :

D = Distance

P_R = Power received

P_T = Power transmitted

λ = Wavelength

4. For additional information contact Steven Coffman at DSN 785-5078 or (513) 255-5078.

Craig Wall

CRAIG WALL, Chief
Design Integrity Branch
Avionics Engineering Division

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